

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office on November 4, 1996

Nancy J. Robins
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Lynn E. Spitler et al.

Serial No.: 08/288,057

Filing Date: 10 August 1994

For: PROSTATIC CANCER VACCINE

Examiner: P. Gambel

Group Art Unit: 1816

DECLARATION OF PHILIP O. LIVINGSTON, MD
PURSUANT TO 37 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, Philip O. Livingston, MD, declare as follows:

1. I am a Associate Professor and in charge of the laboratory of Developmental Tumor Vaccinology at Memorial Sloan-Ketter Cancer Center in New York, New York. I am a member of the Scientific Advisory Board for Jenner Technologies, the assignee of this application, and am also a shareholder in the company. A copy of my *Curriculum Vitae* is attached hereto as Exhibit A.

2. I have reviewed the Declaration Under 37 C.F.R. 1.132 prepared by Dr. Lynn E. Spitler describing the results of a clinical study directed to the use of prostate specific antigen

(PSA) as an active ingredient in an antiprostata cancer vaccine. I am also familiar with the study itself, and with the results that were obtained.

3. The purpose of the study was to obtain initial evidence the vaccines would raise a sufficient cellular immune response to have a beneficial effect with respect to prostate tumors. Such a result could be shown directly by measuring cytotoxic lymphocyte (CTL) generation; however, I am aware that this was not possible in these studies because of problems assaying cytotoxic T cell activity. This problem is widespread in the field, despite occasional reports to the contrary, and a lack of sensitive assays for CTL activity is widely considered to be one of the major obstacles to the development of a new generation of vaccines capable of inducing cytotoxic T cells against tumors. This is due to uncertainty over the optimal assay, the optimal time from immunization to blood drawing, and whether testing for CTL activity in the peripheral blood lymphocytes would ever be capable of reflecting the systemic induction of effective CTLs. Consequently, other assays for T cell immunity have been widely used.

4. The responses measured are understood in the art to be satisfactory substitutes for measuring CTLs. Thus, the proliferation of lymphocytes from two of the patients in response to contact with PSA or in response to peptides representing putative PSA epitopes suggests an appropriate cellular immune response. The ability of PSA or PSA derived peptides to stimulate cytokine production -- i.e., gamma interferon and IL-4 production -- from lymphocytes in these patients indicates that the cellular response is obtained specifically with respect to PSA. The observation of the development of a positive skin test response to PSA in one patient is also consistent with these observations showing the development of cell mediated immunity in this patient.

5. In my opinion, the results obtained in this clinical study provide evidence that the vaccines are likely to be effective in exerting a beneficial effect on patients with prostate tumors or at risk for prostate tumors, though much further work will be required to increase the frequency and potency of the responses.

6. The efficacy shown for the vaccine tested in the foregoing clinical studies further provides evidence that analogous vaccines based on host tissue antigen, such as prostate specific membrane antigen (PSMA) and prostate acid phosphatase (PAP) would behave in a similar

manner. It is also well known that if the entire antigen is effective as a vaccine, portions of the antigen will be effective as well, especially if manipulated by art-known methods to enhance their immunogenicity, such as by coupling them to carrier.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

October 14, 1996

Philip O. Livingston, MD

CURRICULUM VITAE

NAME: Philip O. Livingston, M.D.

DATE OF BIRTH: January 14, 1943

PLACE OF BIRTH: New York, N.Y.

NATIONALITY: U.S.A.

EDUCATION: Princeton University, Princeton, New Jersey
B.A. Biology - 1965

Harvard Medical School, Boston, Massachusetts
M.D. - 1969

HOSPITAL APPOINTMENTS: Cornell Cooperating Hospitals, New York
Intern 7/1/69 - 6/30/70

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Resident 7/1/70 - 6/30/71

New York University Hospital, New York
Fellow - Immunology, 7/1/71 - 6/30/73

U.S. Naval Hospital at Roosevelt Road, Puerto Rico
Lt. Cmdr., Chief of Allergy and Rheumatology Services
1973 - 1975

Memorial Hospital, New York - Fellow -
Department of Medicine - Clinical Immunology Service
7/1/75 - 6/30/77

Memorial Hospital, New York - Assistant Attending
Physician - Department of Medicine
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7/1/77 - 1985

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Exhibit A

TO - 330 1 FROM SENIOR TECHNOLOGIST S O 324 1 1

HONORS AND FELLOWSHIPS: American Cancer Society Junior Faculty
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PUBLICATIONS:

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ABSTRACTS

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